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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/841,132	04/23/2001	Ajay Bhatia	210121.469C8	5589

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EXAMINER	
LI, QIAN J	

ART UNIT	PAPER NUMBER
1632	7

DATE MAILED: 05/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/841,132	Applicant(s) BHATIA ET AL.	
	Examiner Janice Li	Art Unit 1632	

-- The MAILING DATE of this communication appears on th cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 June 2001* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-18* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *detailed action* .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S. C. 121:

Groups 1-4.

Claims 1, 4, and 5 are drawn to an isolated polynucleotide. Each of the groups 1-4 is drawn to a sequence selected from the group consisting of SEQ ID Nos: 358-361, complements, fragments, variants of the polynucleotide, a genetic construct containing the polynucleotide, and host cells transformed with the construct. Classified in class 536, subclass 23.1, and class 435, subclass 320.1, 325, and 455.

Groups 5-8.

Claims 2 and 3 are drawn to an isolated polypeptide comprising an amino acid sequence. Each of the groups 5-8 is drawn to a sequence selected from the group consisting of sequences set forth as in SEQ ID No: 362-365, fragments, and variants. Classified in class 530, subclass 350.

Groups 9-12.

Claim 6 is drawn to an isolated antibody or fragment thereof that specifically binds to a polypeptide sequence. Each of the groups 9-12 is drawn to an antibody capable of binding to a polypeptide sequence selected from the group set forth as in SEQ ID No: 362-365. Classified in class 530, subclass 387.1.

Groups 13-16.

Claim 8 is drawn to a fusion protein or comprising at least one polypeptide sequence. Each of the groups 13-16 is drawn to a polypeptide sequence selected from the group consisting of SEQ ID No: 362-365. Classified in class 424, subclass 185.1.

Groups 17-20.

Claims 7 and 17 are drawn to a method and a kit for detecting *Chlamydia* from a patient sample comprising contacting the sample with a binding agent that binds to a polypeptide, detecting the binding agent, and thus the amount of the polypeptide. Each of the groups 17-20 is corresponding to a sequence set forth as in SEQ ID No: 362-365. Classified in class 435, subclass 7.1.

Groups 21-24.

Claims 10 and 11 are drawn to a method for stimulating or expanding T cells comprising contacting T cells with a polypeptide, and T cells prepared by the methods. Each of the groups 21-24 is corresponding to a sequence selected from the group consisting of SEQ ID No: 362-365. Classified in class 435, subclass 375.

Groups 25-28.

Claims 10 and 11 are drawn to a method for stimulating or expanding T cells comprising contacting T cells with a polynucleotide, and T cells prepared by the methods. Each of the groups 25-28 is corresponding to a sequence selected from the group consisting of SEQ ID No: 358-361. Classified in class 424, subclass 93.2.

Groups 29-32.

Claims 10 and 11 are drawn to a method for stimulating or expanding T cells comprising contacting T cells with an antigen-presenting cell expressing a polynucleotide, and T cells prepared by the methods. Each of the groups 29-32 is correspondent to a sequence selected from the group consisting of SEQ ID No: 358-361. Classified in class 435, subclass 373.

Groups 33-168

Claims 12-14 are drawn to an *in vivo* method for stimulating an immune response or treatment of *Chlamydia* infection comprising administering to the patient a composition selected from the group consisting of one of the following sequences, (**a**) a composition of claim 12; and (**b**) a polynucleotide selected from the group consisting of SEQ ID No: 407-430, 525-559, and 582-598; and (**c**) a polypeptide sequence of any one of SEQ ID No: 431-454 and 560-581. Classified in class 514, subclass 2, 44, or class 424, subclass 93.1, 93.2.

Groups 169-172

Claims 9, 15, and 16 are drawn to a method and a kit for detecting *Chlamydia* from a patient sample comprising contacting the sample with an oligonucleotide that hybridizes to sequences selected from the group consisting of SEQ ID Nos: 358-361, detecting the oligonucleotide, and thus the amount of the polynucleotide. Classified in class 435, subclass 6.

Groups 173-222

Claims 18 is drawn to an *ex vivo* method for treatment of *Chlamydia* in a patient comprising incubating CD4+ and/or CD8+ T cells from the patient with a polypeptide. Each of the groups 219-298 is corresponding to a polypeptide sequence selected from the group consisting of SEQ ID No: 362-365; 431-454, and 560-581; and return the cells back to the patient. Classified in class 424, subclass 93.1.

Groups 223-302

Claims 18 is drawn to an *ex vivo* method for treatment of *Chlamydia* in a patient comprising incubating CD4+ and/or CD8+ T cells from the patient with a polynucleotide. Each of the groups 223-302 is corresponding to a polynucleotide sequence selected from the group consisting of SEQ ID No: 358-361, 407-430, 525-559, and 582-598; and return the cells back to the patient. Classified in class 424, subclass 93.2.

Groups 303-352

Claims 18 is drawn to an *ex vivo* method for treatment of *Chlamydia* in a patient comprising incubating CD4+ and/or CD8+ T cells from the patient with an antigen presenting cell expressing a polypeptide, and return the cells back to the patient. Each of the groups 303-352 is corresponding to a polypeptide sequence selected from the group consisting of SEQ ID No: 362-365, 431-454, and 560-581. Classified in class 424, subclass 93.2.

2. The inventions are distinct, each from the other because of the following reasons.

Inventions 1-16 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, each of the groups 1-16 is drawn to a different product, i.e. polynucleotides, polypeptides, fusion proteins, antibodies, protein-binding agents. The different products are distinct in chemical structure and function, as well as modes of operation when used as therapeutic and diagnostic agents, and they can be used by materially different methods, such as used for a therapeutic composition or in a diagnostic kit.

Inventions 17-352 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, groups 17-32 and 169-172 are drawn to an *in vitro* method, groups 33-168 are drawn to an *in vivo* method, groups 173-352 are drawn to an *ex vivo* method. Each of the groups differs either in the materials used in the process (nucleic acids, polypeptides, fusion proteins, primed T lymphocytes or antigen presenting cells), or the method steps (in vitro, in vivo or ex vivo). The different methods use material different substances, have different method steps, different modes of operation, and have distinct technical considerations, and search criteria.

Inventions 1-16 and 17-352 could be related as product and process of use, respectively. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with

another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, a pharmaceutical composition comprising a nucleic acid (i.e. group VII) could be used in an *ex vivo* process such as group 173, or an *in vivo* process such as group 33, for example, and the different methods could be practiced with materially different products, such as those set forth in group 34, 38, 42, 46, and 50.

Inventions 1-4, 5-8, 9-12, 13-16, 17-20, 21-24, 25-28, 29-32, 33-168, 169-172, 173-222, 223-302, and 303-352 are distinct inventions, because the sequences within each of groups 1-4, 5-8, 9-12, 13-16, 17-20, 21-24, 25-28, 29-32, 33-168, 169-172, 173-222, 223-302, and 303-352 appear to be unrelated sequences with distinct properties. They are different genomic fragments encoding different proteins of the *Chlamydia*, and/or obtained from different strains of the *Chlamydia*, for example. It is applicants' burden to prove otherwise, and to explain how and if the sequences are related.

The differences of the Inventions 1-352 are further underscored by their divergent classification and independent search criteria.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different search criteria, it would impose an undue burden to the Office if all the groups are examined together, thus, restriction for examination purposes as indicated is proper.

3. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is advised that where a single claim encompasses more than one invention as defined above, upon election of an invention for examination, said claim will only be examined to the extent that it reads upon the elected invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Q. Janice Li whose telephone number is 703-308-7942. The examiner can normally be reached on 8:30 am - 5 p.m., Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J. Reynolds can be reached on 703-305-4051. The fax numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of formal matters can be directed to the patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235. The faxing of such papers must conform to the notice published in the Official Gazette 1096 OG 30 (November 15, 1989).

Q. Janice Li
Examiner
Art Unit 1632

QJL
May 15, 2002

JAMES KETTER
PRIMARY EXAMINER